

conditions. The article was misbranded in the above respect while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1) and (2), the labeling of the article failed to bear adequate directions for use and adequate warnings against use in those pathological conditions and by children where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users since the article was essentially a laxative and its labeling failed to bear adequate directions for use as a laxative and failed to warn against the use of the article when symptoms of appendicitis were present; and, Section 503 (b) (4), the labeling of the article bore the statement "Caution: Federal law prohibits dispensing without prescription," and the article was not subject to the provisions of Section 503 (b) (1). The article was misbranded in the above respects when introduced into and while in interstate commerce.

DISPOSITION: October 15, 1953. Default decree of condemnation and destruction.

#### DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\*

4264. Misbranding of phenobarbital tablets, thyroid tablets, anhydrohydroxyprogesterone tablets, dextro-amphetamine sulfate tablets, and tablets containing a mixture of mannitol hexanitrate and phenobarbital. U. S. v. Ken Reynolds Pharmacies, Inc., Kenneth R. Reynolds, and Walter J. Foohey. Pleas of nolo contendere. Fine of \$300 against corporation and \$250 against Kenneth R. Reynolds, plus costs. Sentence suspended against Walter J. Foohey. (F. D. C. No. 33718. Sample Nos. 31208-L, 31209-L, 31211-L, 31329-L, 32503-L, 32504-L.)

INFORMATION FILED: October 4, 1952, Western District of Missouri, against Ken Reynolds Pharmacies, Inc., Joplin, Mo., Kenneth R. Reynolds, president, and Walter J. Foohey, a pharmacist for the corporation.

ALLEGED VIOLATION: On or about July 31, October 1 and 31, and November 2, 1951, while a number of *phenobarbital tablets, thyroid tablets, anhydrohydroxyprogesterone tablets, dextro-amphetamine sulfate tablets, and tablets containing a mixture of mannitol hexanitrate and phenobarbital* were being held for sale at Ken Reynolds Pharmacies, Inc., after shipment in interstate commerce, various quantities of the drugs were repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded. The corporation was charged with causing the acts of repacking and dispensing involved in each of the 6 counts of the information; Kenneth R. Reynolds was joined as a defendant in 5 of the counts; and Walter J. Foohey was joined as a defendant in 1 count.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

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\*See also No. 4263; veterinary preparations, Nos. 4279, 4280.